OCT 1 3 2000

K002858

Summary of Safety and Effectiveness
Line Extension - Xia Spine System

Submission Information

Name and Address of the Sponsor of the 510(k) Submission:

Howmedica Osteonics Corp.
59 Route 17
Allendale, NJ 07401-1677

Contact Person:

Mary-Catherine Dillon
Regulatory Affairs Specialist

Date of Summary Preparation:

August 24, 2000

Device Identification

Proprietary Name:

Xia Spine System

Common Name:

Spinal Fixation Appliances

Classification Name and Reference:

Spinal Interlaminal Fixation Orthosis
21 CFR 888.3050

Spinal Intervertebral Body Fixation Orthosis
21 CFR 888.3060

Pedicle Screw Spinal System
21 CFR 888.3070

Predicate Device Identification

The features of the modified Xia II Polyaxial (PA) Screw are substantially equivalent to the features of the unmodified Xia II PA Screws, which were cleared for marketing via the 510(k) process (K001272).

Device Description

The subject screws are available in 5.5mm, 6.5mm, and 7.5mm diameters and in lengths ranging from 30mm to 60mm (in 5mm increments). The screws consist of a coupling element and a shaft that are preassembled and packaged as one piece. They are manufactured from titanium alloy (Ti-6Al-4V ELI) per ASTM F-136. The subject screws incorporate the following modifications from the current Xia II PA screws: the head of the screw shaft has been reduced from 8mm to 7.7mm; a lip was added above the relief in the coupling element; the cutout in the coupling element was extended distally by 0.5mm.

Intended Use:

The Xia II Polyaxial Screws are intended to be used with the other components of the Xia Spine System.

Indications For Use:

The Xia Spine System is intended for use in the noncervical spine. When used as a pedicle screw fixation system, the Xia Spine System is intended for patients: (a) having severe spondylolisthesis (Grades 3 and 4) at the fifth lumbar - first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine; and (d) who are having the device removed after the development of a solid fusion mass.

When used as a pedicle screw fixation system, the XIA Spine System is also intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

When used as an anterior screw fixation system or a posterior hook and sacral/iliac screw fixation system, the XIA Spine System is indicated for patients with degenerative disc disease which is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, fracture, spinal stenosis, spinal deformities such as scoliosis, kyphosis, lordosis, tumor, pseudoarthrosis or revision of failed fusion attempts.

Statement of Technological Comparison:

The subject Xia II Polyaxial Screws share the same material, intended use, and basic design concepts as that of the predicate Xia II PA Screws. Fatigue and static testing demonstrate the comparable mechanical and endurance properties of the subject components to the predicate components.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 3 2000

Ms. Mary-Catherine Dillon
Regulatory Affairs Specialist
Howmedica Osteonics Corp.
59 Route 17
Allendale, New Jersey 07401-1677

Re: K002858
Trade Name: Xia Spine System
Regulatory Class: II
Product Code: KWQ, KWP, MNH, and MNI
Dated: August 25, 2000
Received: September 13, 2000

Dear Ms. Dillon:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K 002858

Device Name: Xia II Polyaxial Screws

The Xia II Polyaxial Screws are intended to be used as part of the Xia Spine System.

Indications For Use:

The XIA Spine System is intended for use in the noncervical spine. When used as a pedicle screw fixation system, the XIA Spine System is intended for patients: (a) having severe spondylolisthesis (Grades 3 and 4) at the fifth lumbar - first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine; and (d) who are having the device removed after the development of a solid fusion mass.

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

NPO for cmlb

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002858

Prescription Use X OR Over-The-Counter Use ____ (Per 21 CFR 801.109)
(Optional Format 1-2-96)